UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,339	08/03/2000	Carl T Wittwer	7475-66667	9681

23643 7590 08/11/2004

BARNES & THORNBURG
11 SOUTH MERIDIAN
INDIANAPOLIS, IN 46204

EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/631,339	WITTWER ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5-9, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Seubert et al.(US 5,785,926).

With respect to claims 1 and 7, the reference of Seubert et al. discloses a container for holding a fluidic biological sample that includes a receiving portion (94, 84, 54) and a reaction portion (38). A liquid sample positioned within the receiving portion (94, 84, 54) or would be capable of flowing into reaction portion (38). As shown in Figure 17, the receiving portion (94, 84, 54) has a volume greater than the reaction portion (38). The reaction volume is not greater than 1ml or 10,000microliters(See column 5, lines 57-63). With respect to the recited thermal conductivity of the reaction portion, the reference of Seubert et al. discloses that the reaction portion is made of glass which is a material disclosed by the instant specification as a material with the claimed thermal conductivity (See page 53 of the instant specification).

With respect to claims 2 and 3, receiver portion (94) is made of a thermoplastic material and is funnel-shaped (See column 5, lines 33-35).

With respect to claim 5, the reaction volume is not greater than 10microliters (See column 5, line 58).

With respect to claim 6, the glass capillary is inherently transparent.

With respect to claims 8 and 9, the reaction volume is not greater than 1ml and is between about 0.01microliter to about 100microliter (See column 5, line 58).

With respect to claims 14 and 15, the reaction portion has a v:sa ratio of less than 1mm or 0.25 mm (See column 5, lines 57-63).

With respect to claim 16, the glass capillary is inherently optically transmissible for light of the claimed wavelength.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 4, 10, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seubert et al.(US 5,785,926).

The reference of Seubert et al. has been discussed above.

With respect to claims 4, 17 and 18, the use of a stopper positioned within receiving portion (84 or 94) would have been obvious for the known and expected result of sealing off the opening of the capillary device when disconnected from element (54). Sealing with a stopper device would prevent contamination of the contents of the device.

With respect to claim 10, while the preferred capillary diameter of disclosed by Seubert et al. is not within the claimed range, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum capillary dimensions based merely on the intended volumes of samples to be manipulated within the reaction volume.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seubert et al.(US 5,785,926) in view of Bauman et al.(US 3,876,376).

The reference of Seubert et al. has been discussed above.

With respect to claim 12, the reference of Bauman et al. discloses that it is known in the art to seal the ends of a capillary tube during incubation (See column 5, lines 17-23).

In view of this teaching, when incubating the capillary of the primary reference of Seubert et al., it would have been obvious to one of ordinary skill in the art to seal the end as disclosed by the reference of Bauman et al. (See flat tip 12) for the known and expected result of sealing the tube during an incubation step.

8. Claims 7-9 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller (US 5,260,032).

The reference of Muller discloses a sample holding device that includes a receiver portion (12) and a reaction portion (14). The reaction portion (14) has a volume between 0.01microliters and 100miroliters (See column 5, lines 5-24). Two spaced apart parallel plates define the reaction portion.

The reference is silent as to the material of the device.

However, glass is notoriously well known in the art of optical observation devices in view of its recognized optical clarity.

As a result, it would have been obvious to one of ordinary skill in the art to construct the device of the primary reference from an optical quality glass material for the known and expected result of providing the device of an art recognized optical material.

With respect to the recited thermal conductivity of the reaction portion, the reaction portion would be made of glass which is a material disclosed by the instant specification as a material with the claimed thermal conductivity (See page 53 of the instant specification).

With respect to claims 14 and 15, the claimed volume-to-surface area ratio would be met by the dimensions disclosed with respect to the reaction portion (14).

With respect to claim 16, the optical glass would inherently optically transmissible for light of the claimed wavelength.

With respect to claims 17 and 18, the reference of Muller discloses the use of a stopper (80) for the receiving portion.

Response to Arguments

9. Applicant's arguments filed 17 May 2004 have been fully considered but they are not persuasive.

With respect to the rejection of claims 1-3, 5-9, 14 and 15 under 35 USC 102 over the reference of Seubert et al., Applicants argue that the rejection is improper because the Examiner has misinterpreted the device disclosed by the reference of Seubert et al. Applicants stress that the parts with reference numerals 54, 84 and 94 are an actuator, an adaptor and a threaded cap. Applicants stress that the device shown in Figure 17 of Seubert et al. is for sample collection that functions as a pneumatic piston that withdraws fluid from, for example, a microtiter plate and into the capillary tube (38) which is part of the device shown in Figure 17. Applicants argue that the parts with reference numerals 54, 84 and 94 "do not form a receiving portion or a reservoir

for a biological sample" as recited in independent claims 1 and 7. As a result, Applicants conclude that the reference of Seubert et al. cannot anticipate claims 1-3, 5-9, 14 and 15.

In response, the instant claims recite that following positively recited claim limitations:

a) a receiving portion having a first volume wherein the receiving portion is adapted to receive the biological sample therein,

b) a reaction portion, wherein the reaction portion is in fluidic communication with the receiving portion such that the biological sample placed in the receiving portion can travel to the reaction portion and the reaction portion has a volume less than the receiving portion,

c) the reaction portion volume is not greater than 1 milliliter, and

d) the reaction portion must be of a material with a thermal conductivity between 20-35.

The reference of Seubert et al. discloses a device that structurally meets the above claim limitations. First, the reference discloses a number of structures which individually and/or collectively are structurally the same as the claimed receiving portion. These structures include cap (94), adaptor (84) and/or actuator (54). The disclosed structure of the cap (94) and tube (38) when removed from the adaptor would clearly meet the instant claim language. Note the volume in cap (94) for receiving adaptor (84) when disconnected from adaptor (84) would be clearly capable of receiving a biological sample and is clearly in fluid communication with tube (38) such that the sample could travel to the tube (38). Additionally, the volume defined by chambers (86 and 90) of the adaptor (84) also define a volume that is capable of receiving a biological sample and is provided in fluid communication with tube (38) such that the sample could travel to the tube from the volume defined by chambers (86 and 90). Both the volumes defined by the cap (94) alone and/or the volumes defined by chambers (86 and 90) are greater than the volume

defined by the tube (38) (See column 5, lines 18-42 and lines 57-67). Also, the glass capillary disclosed by the reference has a thermal conductivity within the claimed range. See page 53 of the instant specification which refers to page E-6 of the Handbook of Chemistry and Physics. The handbook discloses that laboratory-type glasses inherently fall within this range. Additionally, the reference discloses that the tubes can be used for PCR-type reactions (See column 8, lines 8-39). Finally, while the disclosed device of Seubert et al. is operated and/or used in a different manner than the instantly claimed device, the disclosed structure of the device of Seubert et al. is capable of being used in a manner as intended by Applicants. Note, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the device disclosed by Seubert et al. is capable of being used as intended by applicants and the instant claim language does not preclude a structure the includes structural elements in addition to the ones positively recited in the claim.

With respect to the 35 USC 103 rejections of record involving the reference of Seubert et al. alone or in combination with the reference of Bauman et al., Applicants argue that the rejection is improper because the claims encompassed by these rejections include the same claimed structure recited in independent claims 1 and 7 and therefore the rejection is improper for the same reasons as advanced above with respect to the 35 USC 102 rejection of record.

In response, Applicants' comments are not found to be persuasive for the same reasons as set forth above with respect to the 35 USC 102 rejection of record over the reference of Seubert et al.

With respect to the 35 USC 103 rejection over the reference of Muller, Applicants argue that the rejection is improper because the container disclosed by Muller is not "for holding a fluidic biological sample while undergoing nucleic acid amplification" and the patent does not suggest the use of a glass that has a thermal conductivity of the claimed range.

In response, while the container disclosed by Muller is not specifically recited as being used for nucleic acid amplification, the disclosed structure is the same as that instantly claimed and in the absence of further positively recited structure would be capable of being used for nucleic acid amplification reactions. Note, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the device disclosed by Muller is capable of being used as intended by applicants. With respect to the material of construction, the manufacture of laboratory devices, such as that disclosed by the reference of Muller, out of laboratory quality glass is clearly within the purview of one having ordinary skill in the art. Applicants argue that thermal conductivities of glasses are variable depending on the glass composition, porosity, etc. In response, reference to the Handbook of Chemistry and Physics, which has been incorporated by reference on page 53

of the instant specification, conveys to one of ordinary skill in the art that a majority of known glasses fall within this claimed range, especially, known laboratory glasses such as chemically resistant borosilicate glasses. When constructing the device discloses by the reference of Muller, one of ordinary skill in the art would clearly be motivated to employ a chemically resistant laboratory glass since the preparation of microscope slides involves the use of preparatory chemicals.

For these reasons, applicants' arguments are not persuasive and the rejections of record have been maintained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB